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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,946	02/25/2002	Thomas Guccitault	111701	8746

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Oliff & Berridge  
PO Box 19928  
Alexandria, VA 22320

EXAMINER

YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,946	<b>Applicant(s)</b> GUERITAUT ET AL.	
	<b>Examiner</b> Melanie Yu	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7 January 2002</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Specification***

1. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

### ***Claim Objections***

2. The claims are objected to because the lines are crowded too closely together, making reading and entry of amendments difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).
3. Claim 1 is objected to because of the following informalities: a claim cannot refer to a figure or contain figure labels. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

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4. Claims 1-28 are vague and indefinite for referring to the same label numbers that occur in figures of different embodiments. Furthermore, the labels refer to different components in different figures, therefore it is unclear which embodiment Applicant is claiming as the invention. Label 12 does not appear to point to the same component of the invention in Figure 5 and Figure 6.

5. Regarding claims 1 and 2, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The phrase "any other part" is vague and indefinite because it is unclear which other parts are being excluded.

6. Claims 1, 2, and 8 recite the limitation "the peripheral zone" on page 23 in lines 18-19 and pg. 24 in lines 31-32. There is insufficient antecedent basis for this limitation in the claims.

7. Claims 2, 3, and 25 recite the limitation "the frame of the window" on pg. 24 in lines 10 and 13 and pg. 27 in lines 1-2. There is insufficient basis for this limitation in the claims. Claim 2 is vague and indefinite because it is unclear whether the window is part of the container or whether the window is separate.

8. Claim 2 is vague and indefinite because it is unclear whether the recited parts of the biochip, support, active surface, plurality of ligands, transverse peripheral strip, attachment means, container, and reaction compartments are the same parts as those recited in claim 1.

9. Claims 2, 3, 7-10, 20-23, 25, and 26 are vague and indefinite because it is unclear what applicant is claiming as the window. In Figure 8, the specification labels a part of the window 81 (pg. 17, line 35), which appears to be in a different location than the window labeled as 81 in

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Figures 3A and 4 (pg. 16, line 12). Furthermore, in Figures 2, 3A, 4, and 6, the label **81** for the window does not appear to be pointing to a physical part of the device.

10. Claim 4 is vague and indefinite because it is unclear how the attachment means completely exposes the active face. It is unclear whether Applicant intends for the attachment means to allow for complete exposure of the active face. It is also unclear whether to what the active face is being exposed.

11. Claim 5 is vague and indefinite because it is unclear whether the term “merges” means the active surface becomes part of the active face or whether the active surface is attached to the active face.

12. Claim 7 is vague and indefinite because the phrase “substantially identical” is unclear. It is not specified to what extent or in what aspect the transverse profile of the window must be identical to support of the biochip.

13. Claim 9 is vague and indefinite because it is unclear how the means which allow a surplus of adhesive at the level of the window of the container and if the beveled shape is part of the window.

14. Claim 10 recites the limitation "interstice" on pg. 24 in line 38. There is insufficient antecedent basis for this limitation in the claim. Claim 10 is vague and indefinite because it is unclear whether the recited dimensions are of the interstice, the border of the window, or the transverse strip of the biochip.

15. Claim 12 is vague and indefinite because it is unclear what two opposite zones of the transverse strip encompass. It is unclear if the transverse strips being attached are on the biochip and the container or if the transverse strips are on the biochip only.

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16. Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

17. Claim 21 is vague and indefinite because it is unclear how the attachment means exert a pressure on the transverse strip without any applied force.

18. Claims 21-24 recite "at the level of the window" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim. No window is recited in claim 1, so claim 21 should be dependent on claim 2. The phrase "at the level of the window" is vague and indefinite because it is unclear how the attachment means have flexible means at the level of the window.

19. Claim 23 is vague and indefinite because it is unclear what is meant by the phrase "the cross-section of which is substantially triangular". It is unclear whether the phrase refers to the cross-section of the claws, the biochip, or the window. Furthermore, it is unclear whether the container or flexible means comprises claws.

20. Claim 26 recites the limitation "the positioning means" on pg. 27 in lines 5-6. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 27 is vague and indefinite because it is unclear whether the ultraviolet radiation is applied on at least one of the faces of the analytical device or the adhesive seal is on at least one of the faces of the analytical device.

22. Claim 28 is vague and indefinite because it is unclear whether the ligands are contained in the active surface or whether the ligands are attached to the active surface.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 11-16, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Besemer et al. (EP 0 695 941).

With respect to claims, 1-5, 7, 14, and 19, Besemer et al. teach a device for analyzing at least one analyte, comprising a biochip comprising a support (wafer, col. 5, lines 35-40); an active face being rectangular or square (Fig. 1b, biochip 145 is a square), and comprising an active surface onto which are disturbed and attached a plurality of ligands wherein the ligands are nucleic acids (Fig. 1b; col. 5, lines 41-47; col. 4, lines 8-18); at least one face opposite the active face, and a transverse peripheral strip (col. 6, lines 46-48); a container comprising a window with a frame edge parallel to the transverse strip of the biochip (Fig. 27a, window, 2741 is parallel to the edge of the biochip 2790; Fig. 27b, edge of biochip 2790 parallel to edge of window 2741 meets 2705) and a transverse profile substantially identical to that of the support of the biochip (Fig. 27b, transverse profiles of 2770 and 2790), and the biochip attached to the container via an attachment means placed on both sides of the active face of the biochip (Fig. 27b attachment 2791 on both sides of active face 2795, col. 17, lines 10-20) with the active face of the biochip is merged with the active surface of the container (Fig. 27b, active face 2795 is merged with the container at the active surface 2705 above 2790); the container and biochip delimiting a reaction compartment (Fig. 27b, 2710; col. 7, lines 18-29); and the attachment

means connecting on the transverse side of the biochip, and completely exposing the peripheral zone of the active face of the biochip and the frame of the window of the container (Fig. 27b; active face **2795** exposed to reaction chamber **2710** and window frame **2741**). The face opposite the active face is considered to be the back of the wafer, which must have a face on the back because the wafer is described as having a thickness.

With respect to claims 6, 8, 9, 11-13, and 20, Besemer et al. teach the attachment means being an adhesive cured by ultraviolet radiation (col. 11, lines 34-35) extending along the entire transverse strip and connecting two opposite zones of the transverse strip to the container and the container having a beveled shape at the level of the window to allow a surplus of adhesive to be stored without it overflowing onto the peripheral zone of the biochip (col. 8, lines 22-27; col. 9, lines 18-31). Besemer et al. also teach a concavity present on all or part of the surroundings of the window of the container (col. 15, lines 1-22 and 30-40).

With respect to claims 15 and 16, Besemer et al. teach the reaction compartment arranged so as to bring a liquid medium, subjected to the analysis, and the active surface of the biochip into contact (Fig. 27b, fluid flows into reaction compartment **2710** and subjects the liquid to analysis on the active surface **2795**; col. 18, lines 21-33). Besemer et al. also teach attachment means ensuring that the reaction compartment is leak tight with respect to the outside (col. 15, lines 35-40; col. 16, lines 6-20).

With respect to claims 21-23, Besemer et al. teach an attachment means comprising means which are flexible at the level of the window of the container, and exert a pressure on the transverse strip of the biochip (col. 15, lines 1-5; col. 16, lines 6-20) and an intermediate component inclined relative to the opposite face of the biochip and an end component



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substantially perpendicular to said opposite face, said end component exerting a pressure on the transverse strip of the biochip (col. 16, lines 6-20). Besemer et al. also teach an attachment comprising means that are flexible and comprise claws having a substantially triangular cross-section (Fig. 20a and b, 2015; col. 15, lines 41-56).

With respect to claims 24-28, Besemer et al. teach a liquid adhesive seal distributed between the transverse strip of the biochip and the container and cured by ultraviolet radiation (col. 9, lines 23-25) with the biochip positioned relative to the container so as to place the transverse strip opposite the frame of the window of the container (Fig. 27b, transverse strip 2970 is opposite the window 2741 meets 2705), maintaining the positioning of the biochip by applying a vacuum (col. 12, lines 2-10), positioning a mask between the biochip and the ultraviolet radiation in order to protect the ligands in the active surface (col. 12, lines 18-21), and applying ultraviolet radiation to the adhesive seal on at least one of the faces of the analytical device (col. 12, lines 22-29).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 10, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besemer et al. (EP 0 695 941).

Besemer et al. teach all of the limitations of the device for analyzing at least one analyte, but fail to teach the specific dimensions of the transverse strip, the dimensions of the active surface, and the percentage of the surface area covered by the active face.

With respect to claim 10, Besemer et al. fail to specifically recite the dimension of the transverse strip being between 2 mm and 0.05 mm. With respect to claims 17 and 18, Besemer et al. teach the active surface area of the biochip being exposed to a reaction compartment, and being smaller than the cross-sectional area of the reaction compartment, 217 mm<sup>2</sup> (col. 7, line 57; Fig. 27b, length of the active surface **2795** is smaller than the length of the cavity **2710**), but fail to teach the specific limitations of an active surface area less than 100 mm<sup>2</sup> and the active surface of the biochip representing at least 75% of the active face of the biochip. However, it would have been obvious to one having ordinary skill in the art to fabricate the biochip of Besemer et al. within a particular dimension in order to optimize the performance of the biochip since it has been held that where general conditions of the claim are disclosed in the prior art, discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of

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workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claim 10, 16, and 17 are for any particular purpose or solve any stated problem, and the prior art teaches that the thickness of the wafer used for the biochip can vary depending on the composition (col.6, lines 46-48), and the active surface of the biochip is smaller than the area of the cavity,  $217 \text{ mm}^2$  (Fig. 27b, length of the active surface **2795** is smaller than the length of the cavity **2710**), and the prior art allows for chips of various sizes to be mated to the container (col. 7, line 57; col. 17, lines 21-26), absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art of designing devices for analysis of analyte.

### ***Conclusion***

No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Woudenberg et al. (US patent 6,126,899) teach a device for detecting or quantifying one or more selected analyte with detection chambers with immobilized ligands, but fail to teach a separate biochip adhered to a container. Wu et al. (US patent 6,716,642) teach biochips employing magnetic forces with immobilized ligands and the chips adhered to the substrate, but fail to teach curing of the adhesive by UV radiation.

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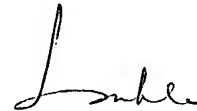
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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